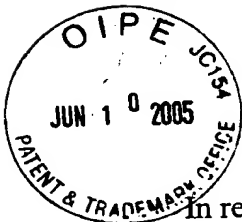


DOCKET NO.: JJPR-0027 (ORT-1462)  
Application No.: 09/921,516  
Office Action Dated: September 21, 2004

PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
**Loretta Itri et al.**

Confirmation No.: 6089

Application No.: 09/921,516

Group Art Unit: 1642

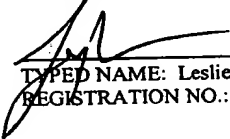
Filing Date: August 1, 2001

Examiner: **Karen A. Canella**

For: **Improved Anti-Viral and Anti-Tumor Chemotherapy by Administration of Erythropoietin**

DATE OF DEPOSIT: March 21, 2005

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

  
TYPED NAME: Leslie E. Aberman  
REGISTRATION NO.: 54,836

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

REPLY PURSUANT TO 37 CFR § 1.111

In response to the Official Action dated September 21, 2004, reconsideration is respectfully requested in view of the amendments and/or remarks as indicated below:

- ☐ Amendments to the Specification
- ☒ Amendments to the Claims are reflected in the listing of the claims which begins on page 2 of this paper.
- ☐ Amendments to the Drawings .
- ☒ Remarks begin on page 3 of this paper.

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This listing of claims will replace all prior versions, and listings, of claims in the application.

**Listing of Claims:**

1-19. Canceled

20. (Original) A method comprising the steps in any order:

- a) administering an anti-viral regimen comprising an interferon and ribavirin to a subject in need thereof;
- b) measuring hemolysis of said subject's red blood cells;
- c) adjusting the amount of ribavirin provided to the subject such that a desired amount of hemolysis occurs; and
- d) administering a therapeutically effective amount of erythropoietin (EPO) to the subject, wherein the erythropoietin improves an ability of the subject to maintain or increase the ribavirin dose.

21 (Original) The method of claim 20 wherein the desired amount of hemolysis is a reduction in the hemoglobin levels by about 20% within about one week of ribavirin administration.

22. (Original) The method of claim 20 wherein the amount of ribavirin administered is greater than 1200 mg/day for a subject weighing greater than 75 Kg or greater than 1000 mg/day for a subject weighing less than 75 Kg.

23-28. Canceled

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### REMARKS

Claims 1-28 are currently pending in the present application. Claims 1-6 are rejected and claims 7-19 and 23-28 are withdrawn from consideration. Applicants wish to thank the Examiner for indicating that claims 20-22 are directed to allowable subject matter. In order to advance the present case to allowance, and without acceding to the propriety of the rejections, Applicants have canceled claims 1-19 and 23-28. Applicants reserve the right to pursue the subject matter of claims 1-19 and 23-28 in future continuing applications. After entrance of the present amendments, claims 20-22 will be pending.

A Supplemental Information Disclosure Statement is submitted herewith.

### ADMINISTRATIVE MATTERS

It was agreed during an interview conducted on March 18, 2005 with Supervisory Examiner Jeffrey Siew that the time for responding to the Office Action mailed September 21, 2004 would be restarted as the Action was mailed to the wrong correspondence address. Attached as Appendix A is a printout from PAIR indicating that the time for response was restarted on March 18, 2005. Applicants believe that no extension fee is due at this time and that patent term will not be negatively impacted.

The foregoing represents a *bona fide* attempt to advance the present case to allowance. Applicant submits that this application is now in condition for allowance. Accordingly, an indication of allowability and an early Notice of Allowance are respectfully requested. If the Examiner believes that a telephone conference would expedite prosecution

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of this application, please telephone the undersigned at 215-568-3100.

Date: *March 21, 2005*

  
\_\_\_\_\_  
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**Paper:**

Reply Transmittal Letter (in duplicate) w/First Class Mail  
Certification; Reply Pursuant to 37 CFR §1.111; Applicant-Initiated Interview  
Summary; Appendix "A"; Supplemental Information Disclosure Statement; Form  
PTO-1449 Modified with attached references listed (73-91); Check in the amount  
of \$180.00 to cover cost of SIDS and Return Postcard all via First Class Mail.

**Applicant(s):**

Loretta Itri, et al.

**Title:**

Improved Anti-Viral And Anti-Tumor Chemotherapy By  
Administration Of Erythropoetin

**Application No.:**

09/921,516

**Filed:**

August 1, 2001

**Docket No.:**

JPR-0027(ORT-1462)

**Date Sent:**

March 21, 2005

**Sent By:**

Aberman/AHampton

